

K062299

1072

VII. Section 10 – 510(K) Summary

This summary of 510(K) substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92

1. Applicant's Name and Address

Whip Mix Corporation,
Lab Services Division
361 Farmington Ave.
Louisville, Kentucky 40217
Telephone Number: 502-634-1451
Fax Number: 502-634-4512
Contact Person: Frederick T. Kapp
Quality Manager

NOV 20 2008

2. Name of Device

Trade Name: Vericore™ Abutment
Common Name: Endosseous dental implant abutment
Classification Name: Endosseous dental implant abutment
21 CFR 872.360
Product code: NHA

3. Legally Marketed Device to which Equivalence is claimed(Predicate Device) Atlantis Zirconia Abutments for Replace K062277

4. Description of Device

The Devices covered in this submission are abutments which are placed on the dental implant to provide support for a prosthetic restoration.

Vericore Abutments are made from biocompatible yttria-stabilized zirconia blocks. The abutment screws and adaptors are made from Titanium grade Ti-6Al-4V for the screws and Grade 4 for the adaptors. The abutment is placed over the implant and is mounted on to the implant with an abutment screw; an abutment adaptor will be added between the implant and the abutment. The abutment adaptor is intended to interface between the abutment and the implant allowing the abutment to meet with and be sealed to the parts of the implant that can not be milled into the abutment. The abutments are compatible with the following implant systems:

Replace- Narrow (3.5mm), Regular (4.3mm), Wide (5.0mm) and 6mm
Southern Trilock – Narrow (3.5mm), Regular (4.3mm) and Wide (5.0mm)

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5. Intended use of the Device

The intended uses of the devices covered by this submission are abutments which are placed on the dental implant to provide support for a prosthetic reconstruction. The Vericore abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support a single and multiple tooth prosthesis, in the mandible or maxilla. The abutment screw is intended to secure the abutment to the endosseous implant.

6. Basis for Substantial Equivalence

Vericore abutments are substantially equivalent to Atlantis Zirconia Abutments for Nobel Replace (K06227). Both devices are Zirconia abutments designed to fit the Nobel Replace implants.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David J. Steinbock
Vice President Corporate Services
Whip Mix Corporation
Lab Services Division
361 Farmington Avenue
Louisville, Kentucky 40217

NOV 20 2008

Re: K082299

Trade/Device Name: Vericore™ Abutment in Zirconia for Implant Systems
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 12, 2008
Received: November 12, 2008

Dear Mr. Steinbock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082299

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Indications for Use

510(k) Number:

Device Name: Vericore™ Abutment in Zirconia for Implant Systems, See list below.

The Vericore Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The abutment is placed over the implant and is mounted on to the implant with an abutment screw; an abutment adaptor will be added between the implant and the abutment. The abutment adaptor is intended to interface between the abutment and the implant allowing the abutment to meet with and be sealed to the parts of the implant that can not be milled into the abutment.

This device is compatible with the following manufacturers' implant systems: Nobel Biocare, Southern Trilock.

This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Also highly angled abutments (i.e. 28 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.

Replace- Narrow (3.5mm), Regular (4.3mm), Wide (5.0mm) and 6mm
Southern Trilock – Narrow (3.5mm), Regular (4.3mm) and Wide (5.0mm)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF
NEEDED)

Susan Runde
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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